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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,230	09/27/2001	Gil H. Choi	PB481US	3043

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Human Genome Sciences Inc
9410 Key West Avenue
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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

MS

Office Action Summary**Application No.**

09/830,230

Applicant(s)

CHOI ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9,10,15-17,19 and 21-45 is/are pending in the application.
 4a) Of the above claim(s) 9-10, 15-17, 19 and 21 is/are withdrawn from consideration.
 5) ☒ Claim(s) 36-40 and 45 is/are allowed.
 6) ☒ Claim(s) 22-33,41,43 and 44 is/are rejected.
 7) ☒ Claim(s) 34,35 and 42 is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 11252003.
 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) ☐ Notice of Informal Patent Application (PTO-152)
 6) ☐ Other: _____.

DETAILED ACTION

Following the entry of the amendment filed 11/25/2003, the claims 9-10, 15-17, 19, and 21-45 are pending. It is noticed that claims 1-8 are canceled in the claims and in the Remarks it states that claim 1 will be pending. Clarification is required.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 22-45 in Paper No. 11252003 is acknowledged. The applicant traverses the restriction on the grounds that there would not be serious burden on the examiner to search and examine the subject matter of all the groups together, at least for a single nucleic acid or amino acid sequence. The applicant's argument has been fully considered but is not deemed to be persuasive. A *prima facie* case of burden has been shown because the inventions have acquired a separated status in the art as shown by their different classifications.

Because the restriction requirement is deemed proper, it is herein made FINAL.

2. Claims 9-10, 15-17, 19 and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups. An action on claims 22-45 follows.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 22-31 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses the polynucleotide, SEQ ID NO: 625 encodes the *B. burgdorferi* peptides amino acid sequence SEQ ID NO: 627. The specification proposes to discover other members of the genus, but there is no description of the mutational sites that exist in nature and there is no description of how the structure of the isolated polynucleotide relates to the structure of any mutants (See pg. 14, lines 11-23 of the specification). In the present state of the art the structure of one does not provide guidance to the structure of others. Thus, one of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claim.

5. Claims 22-31 and 43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide SEQ ID NO: 625 encodes the *B. burgdorferi* peptides amino acid sequence SEQ ID NO: 627, does not reasonably provide enablement for an isolated polynucleotide encoding an amino acid sequence at least 95% identical to the full length amino acid sequence of SEQ ID NO: 627. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the

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presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance presented as regards the sequence of the isolated polynucleotide encoding an amino acid sequence at least 95% identical to the full length amino acid sequence of SEQ ID NO: 627. Also, there is no data in the specification supporting the mutational sites that exist in the isolated polynucleotide encoding an amino acid sequence at least 95% identical to the full length amino acid sequence of SEQ ID NO: 627. While the relative skill in the art is very high, there is no predictability as to what sequences are present on the claimed polynucleotide encoding an amino acid sequence at least 95% identical to the full length amino acid sequence of SEQ ID NO: 627.

The specification provides working example using the polynucleotide sequence listed in table 1 to express *Borrelia* polypeptide in *E. coli* (See pg. 43-44 of the specification). The specification does not provide example using the isolated polynucleotide encoding an amino acid sequence at least 95% identical to the full length amino acid sequence of SEQ ID NO: 627 to express *Borrelia* polypeptide. Finally, as regards the nature of the invention, the claimed invention is drawn to polynucleotides. Polynucleotides are a chemical compound with an exact nucleotide sequence and claims drawn to polynucleotides should clearly define the nucleotide sequence for which protection is desired. The breadth of these claims includes any polynucleotide sequence encoding an amino acid sequence at least 95% identical to the full length amino acid sequence of SEQ ID NO: 627. Accordingly, it is concluded that undue

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experimentation is required to make the invention as it is claimed. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 32-33, 41 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Marconi et al. (Journal of Bacteriology, 1996, Vol. 178(19), pg. 5615-5626).

Claim 32 is drawn to an isolated polynucleotide which encodes at least 30 contiguous amino acid residues of SEQ ID NO: 627.

Marconi et al. teach an isolated polynucleotide which encodes at least 30 contiguous amino acid residues of SEQ ID NO: 627 (See pg. 5618, fig. 2 and the attached search report).

Claim 41 is drawn to an isolated polynucleotide comprising a nucleic acid sequences encoding an epitope-bearing portion of the amino acid sequence of SEQ ID NO:627

The teachings of Marconi et al. also read on the limitation of claim 41 that an isolated polynucleotide comprising a nucleic acid sequences encoding an epitope-bearing portion of the amino acid sequence of SEQ ID NO:627 since there is no specific nucleic acid sequence recited which encodes the epitope-bearing portion of the amino acid sequence of SEQ ID NO:627 in the claim.

Claim 44 is drawn to a method of detecting *B. burgdorferi* under hybridization condition.

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Macron et al. further teach using PCR amplification and Southern blot hybridization to analyze the nucleic acid sequence from *B. burgdorferi* with the primers or probes from the gene of *B burgdorferi* (See pg. 5616, column 1, and 2).

Allowable Subject Matter

8. Claims 36-40 and 45 are allowed.
9. Claims 34-35 and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Summary

10. Claims 22-35 and 41-44 are not allowable.
- 11 Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.


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Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

March 10, 2004



ETHAN WHISENANT
PRIMARY EXAMINER